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FDA's Dockets Management Branch (HFA-305)
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To Whom It May Concern:

I am writing in response to CVM's request for comments concerning their discussion draft entitled: " Proposals To Increase The Availability Of Approved Animal Drugs For Minor Species And Minor Uses ". I am providing the following comments to the particular questions that CVM has asked:

Page 16: The proposed modification of extralabel provisions should provide adequate and appropriate temporary relief until approved products are made available. The ten year sunset provision is an adequate time period to allow pursuit of an approval.

The proposed modifications should be extended to include reproductive hormones and implants.

Page 18: The suggested strategies currently outlined should be sufficient to remove the existing direct regulatory disincentives. Increased enforcement activities should be directed toward the distributor level rather than the consumer level. Except for additional governmental funding to be directed toward product registration and approval, I do not believe an additional disincentive exists.

Page 20: Within USDA's Agricultural Research Service (ARS), increased congressional funding for the Stuttgart National Aquaculture Research Center, which has as part of its mission: to conduct research in therapeutic evaluations for the registration of chemicals and drugs for aquaculture, would assist in minor use research.

Page 21: I believe the proposed model would provide a useful supplement to the existing NRSP-7 program.

The proposed data base would be useful to parties interested in furthering the approval of minor use products but I do not know how it might be developed most cost-effectively.

Page 24: Extended exclusivity is more important than the risk of increased drug costs as it acts as an incentive for a company to pursue approval. If drugs are not approved then their cost is irrelevant.

Extending the period of exclusivity for all the claims of the product would be a greater significant incentive, however, as stated, the 100% tax credit would be the greatest incentive of all.

Page 25: I believe it is fair to require the sharing of data as the major problem is "a lack of incentive to share" and not one of competition.

Potential liability could be avoided by requiring any company seeking data to sign a relief form that states such data are "Use At Your Own Risk" type data, thereby releasing the parent company from any liability.

A statutory designation of "minor use animal drug" should have been obtained at the same time the "human orphan drug" designation was established. This oversight should be corrected legislatively as it definitely would be useful.

Page 27: The incentives associated with this strategy are necessary component of the overall proposed "Minor Use Animal Drug Program". The human orphan drug program would not have been so successful without these same incentives. Page 30: The proposed constraints upon conditional approval as outlined would provide sufficient consumer protection and still provide adequate incentive to pursue a conditional drug approval to final approval. The proposed process should be considered for minor uses in food animals at a later date after a history is established with non-food animals.

Page 34: Animal caretakers will find drugs approved under the proposed alternate standard acceptable, because in many cases these may be the only approved drugs available to them.

The affected industries have the expertise but may not initially have the resources to fund the expert review panels. However, I believe said funds can be found if the proposed process is implemented.

The proposed process should be restricted to minor uses in non-food animals at this time.

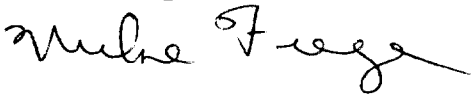
Page 36: Non-governmental input should facilitate equivalency determinations. There are sufficient numbers of foreign approvals to justify establishing this program (ie. Japan).

The proposed differences in approval, standards, processes and data requirements between major and minor species should definitely be included in international harmonization activities.

In conclusion, I would like to commend the CVM for a job well done! The many ideas proposed in this draft represent logical compassionate solutions to the lack of approved animal drugs for minor species and minor uses.

Hopefully, many if not all of the proposed actions within this draft can be implemented, but the thing that is most encouraging to me is the positive approach that CVM has taken in attempting to address a very serious problem. I intend to personally contact my Congressional representatives to express my appreciation of the approach CVM has taken and to ask their support of any legislative changes, funding, etc. that may be required.

Sincerely,



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